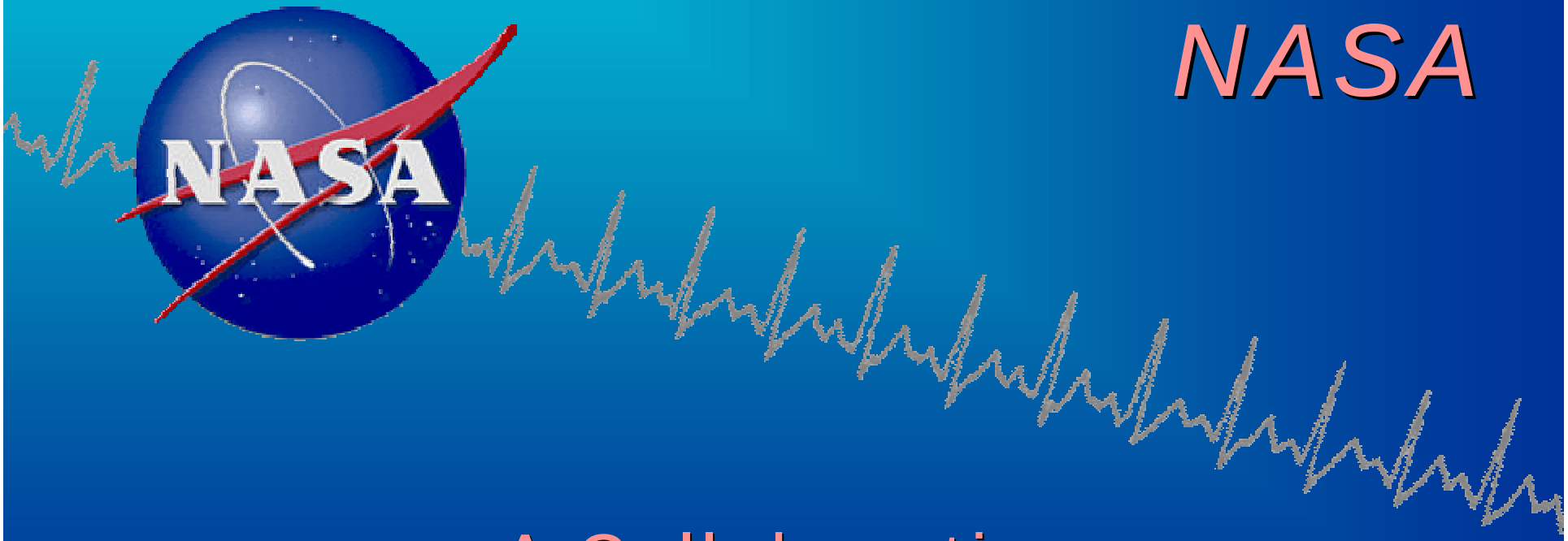
The DeBakey Ventricular Assist Device (VADä)

&

NASA



A Collaboration

Video courtesy of MicroMed Technology, Incorporated

Contents

Pathophysiology

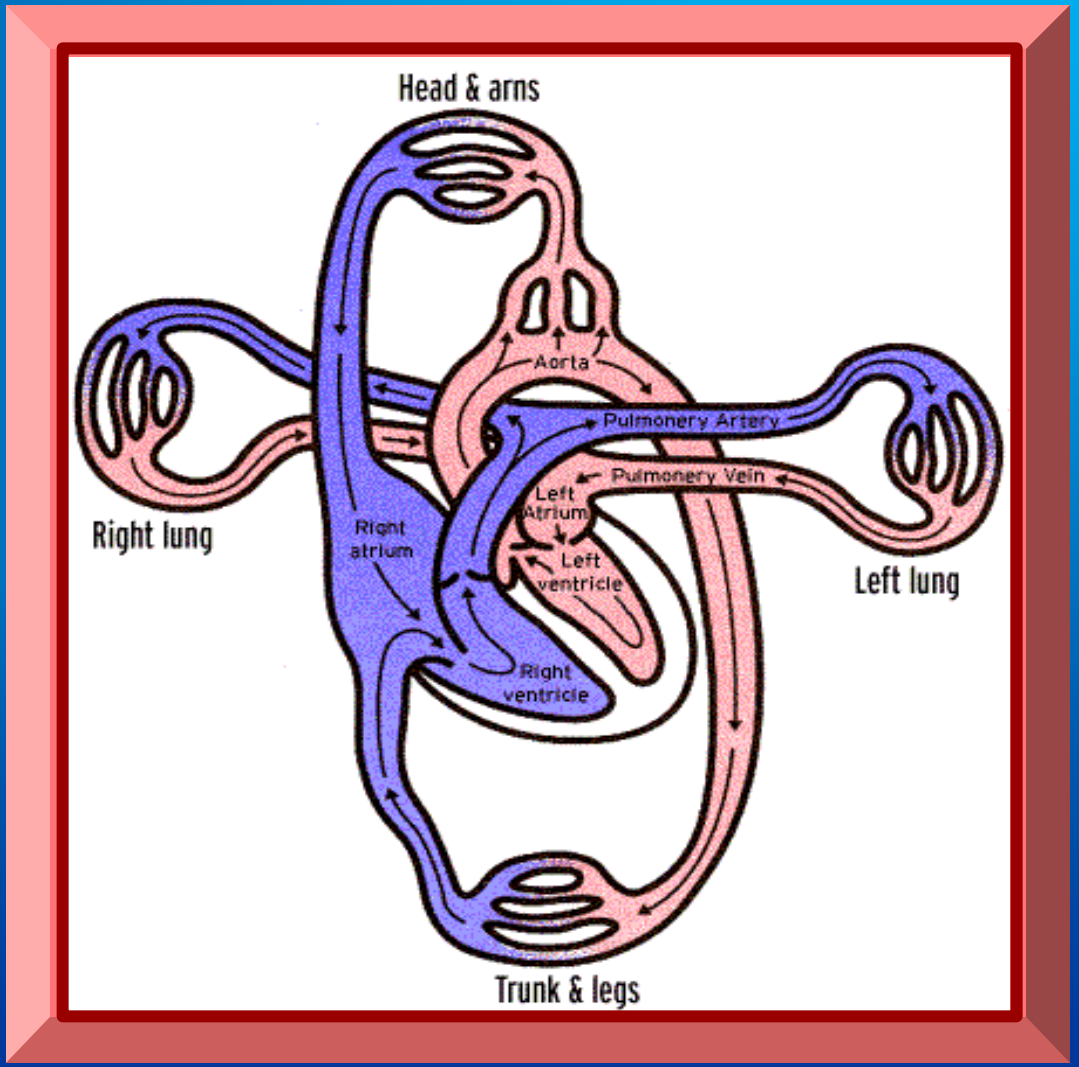
Cardiovascular disease (CVD): the inability of the heart to pump adequate blood volume

CVD is induced by multiple causes

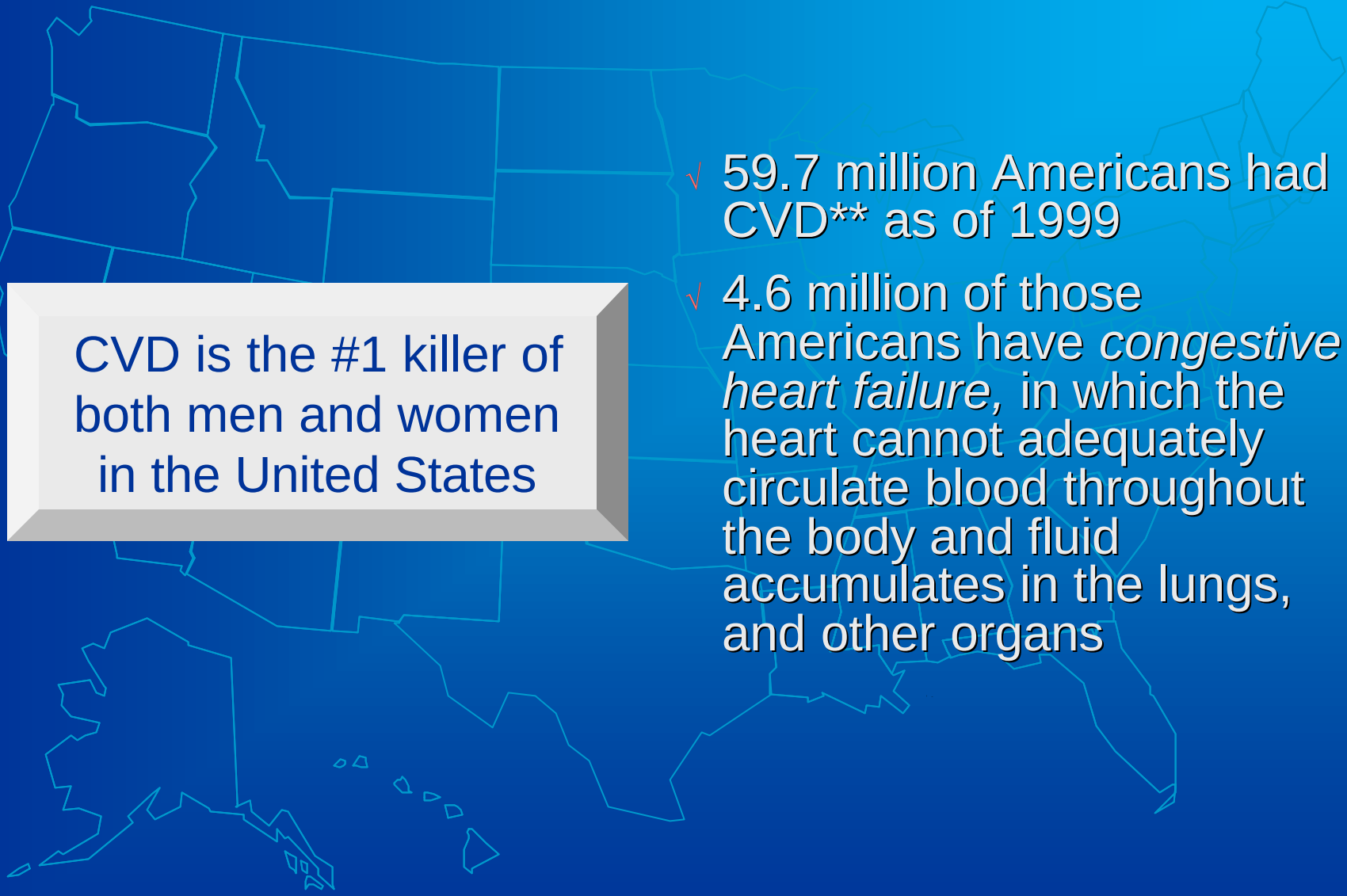
- Disturbances in contraction of the cardiac muscle
- Overload of the ventricle, the muscular chamber responsible for pumping blood to the entire body
- Disorders that affect normal filling of the heart

Model of Heart

A schematic showing blood flow through the body



Demographics

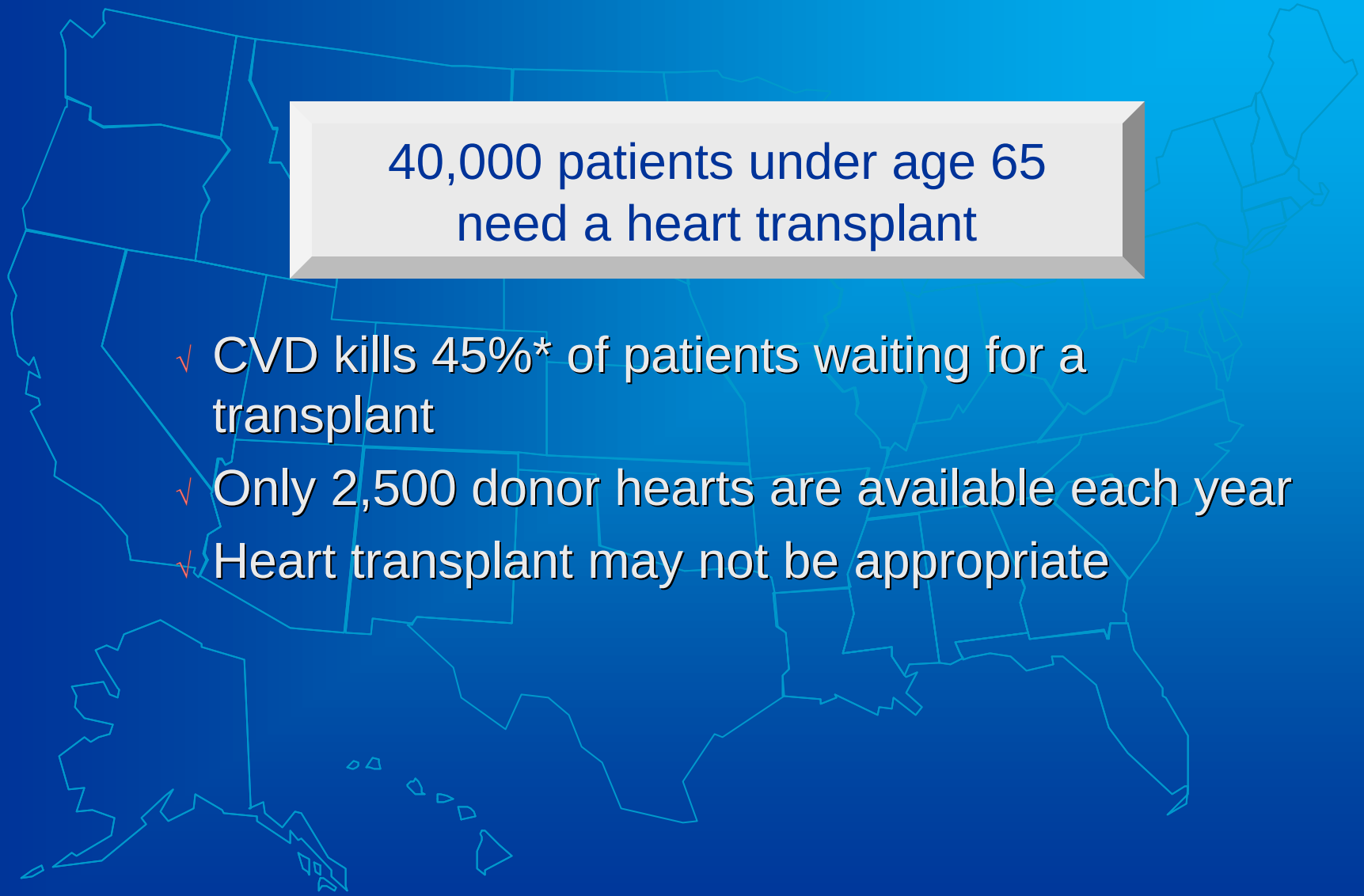


CVD is the #1 killer of both men and women in the United States

- 59.7 million Americans had CVD** as of 1999
- 4.6 million of those Americans have *congestive heart failure,* in which the heart cannot adequately circulate blood throughout the body and fluid accumulates in the lungs, and other organs

**American Heart Association, 1999

Demographics



40,000 patients under age 65 need a heart transplant

- CVD kills 45%* of patients waiting for a transplant
- Only 2,500 donor hearts are available each year
- Heart transplant may not be appropriate

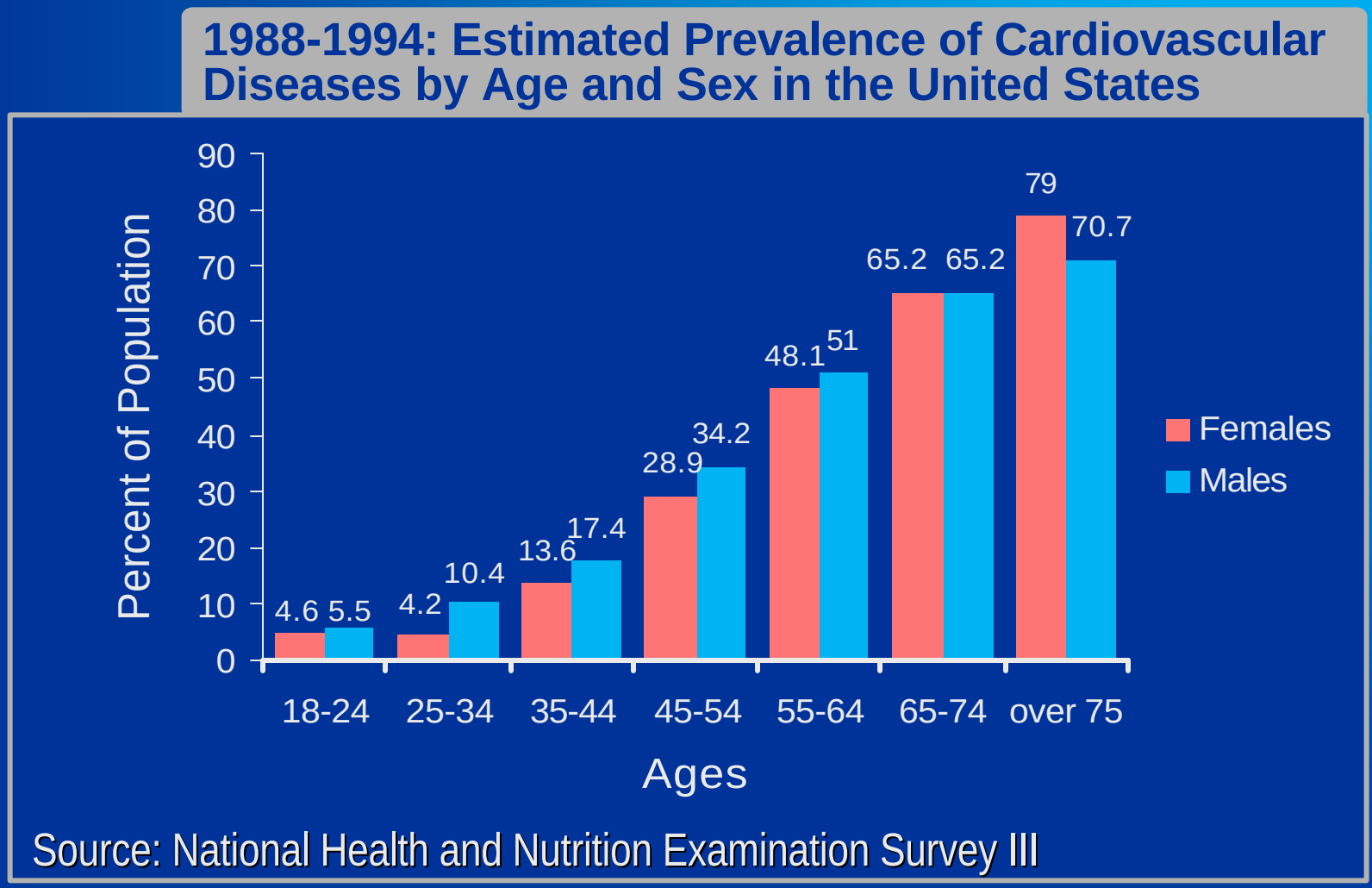
*Based on the Framingham Heart Study

National Annual Cost

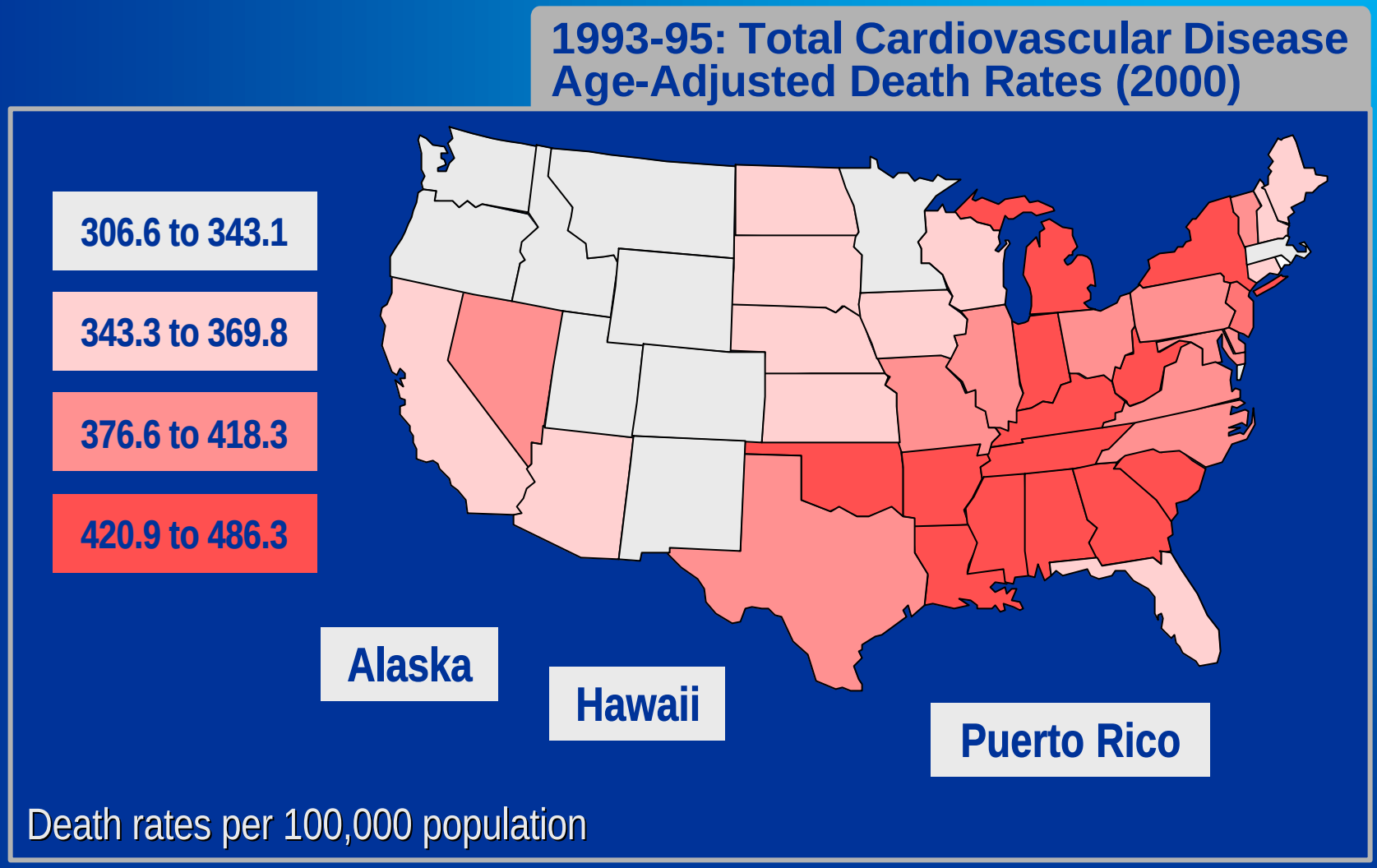
The national, annual cost of congestive heart failure is

21 Billion dollars

CVD by Age and Sex

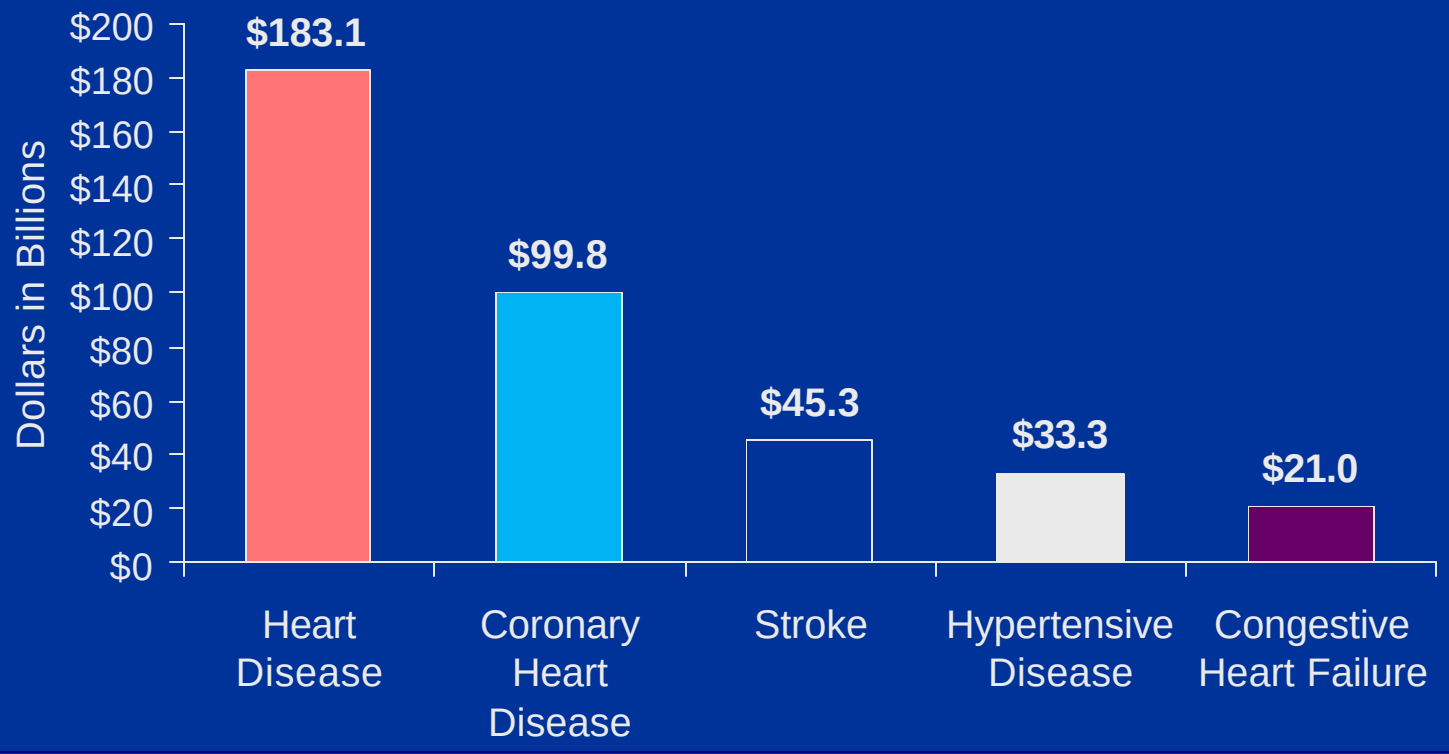


CVD by State


1993-95: Total Cardiovascular Disease
Age-Adjusted Death Rates (2000)
306.6 to 343.1
343.3 to 369.8
376.6 to 418.3
420.9 to 486.3
Alaska
Hawaii
Puerto Rico
Death rates per 100,000 population

Medical Costs

1999: Estimated Direct and Indirect Costs of Cardiovascular Diseases and Stroke in the United States



Statistics from the American Heart Association

Device History

1937
Dr. DeBakey invents the first pump to model heart function

1952
Early versions of mechanical pumps are created

1989
A NASA engineer, David Saucier, suggests to Dr. DeBakey that NASA and Baylor College of Medicine collaborate to develop a heart bypass pump using Space Shuttle technology

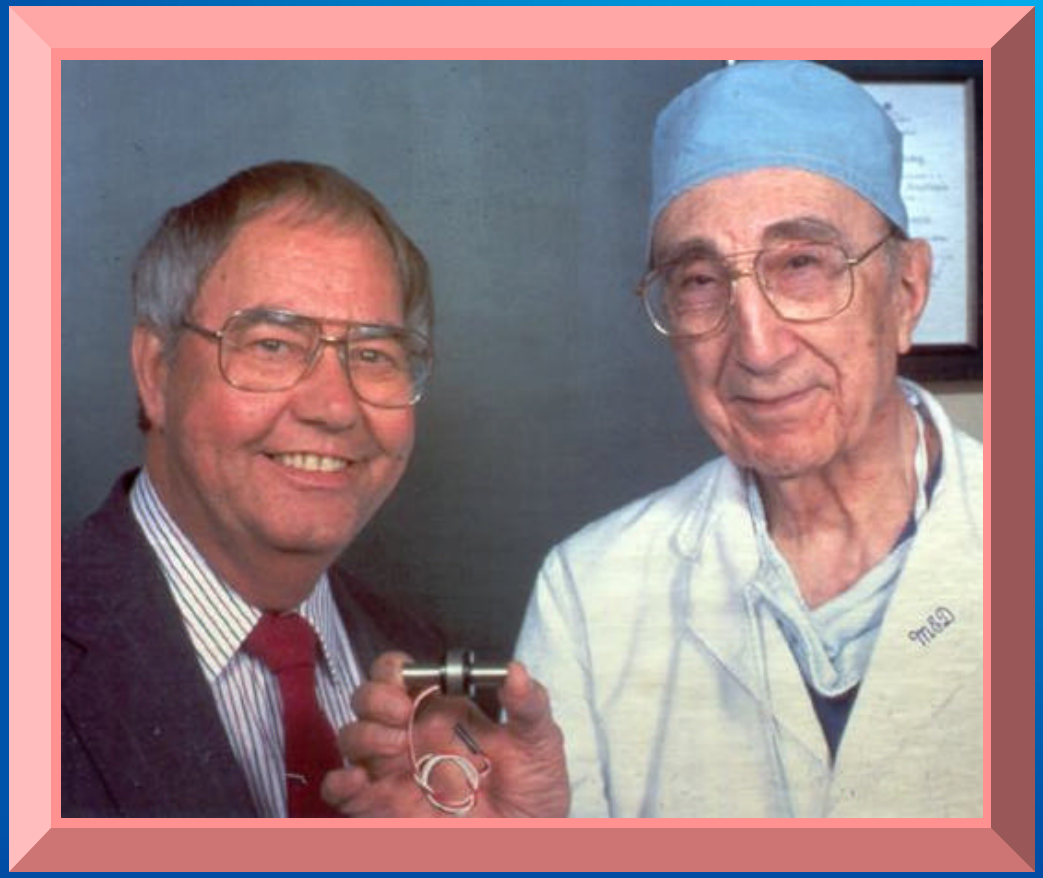
1994
Initial prototypes are promising

1996
MicroMed™ obtains a NASA license and secures venture capital

1998
A sophisticated, implantable device is approved for human testing in Europe

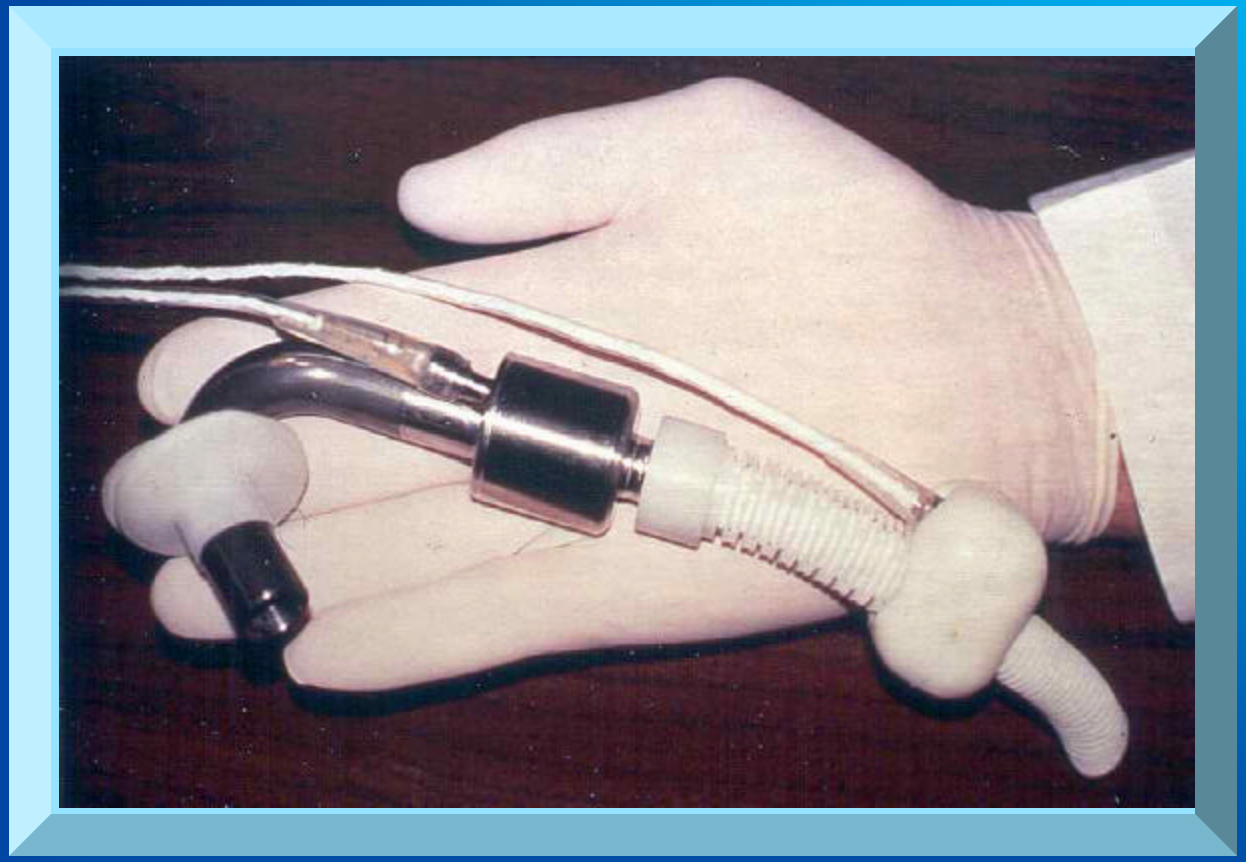
2000
Clinical trials begin in the U.S.A.

Device History



Dr. DeBakey and David Saucier exhibit the implantable Ventricular Assist Device (VAD™)

Device History

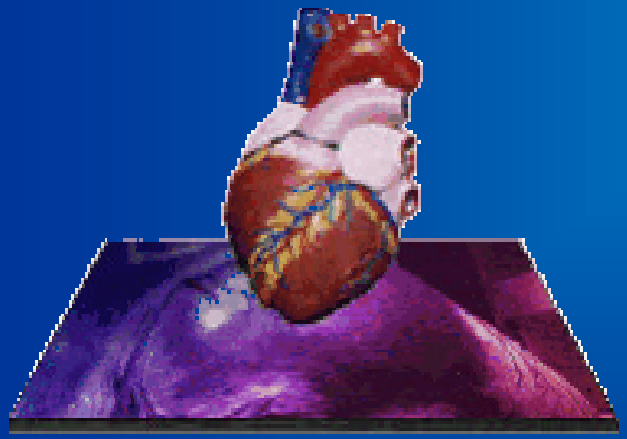


Early VAD™

Commercial Interest

Potential benefits: 50,000 - 60,000 adults and children annually in the United States

Multiple medical uses include:



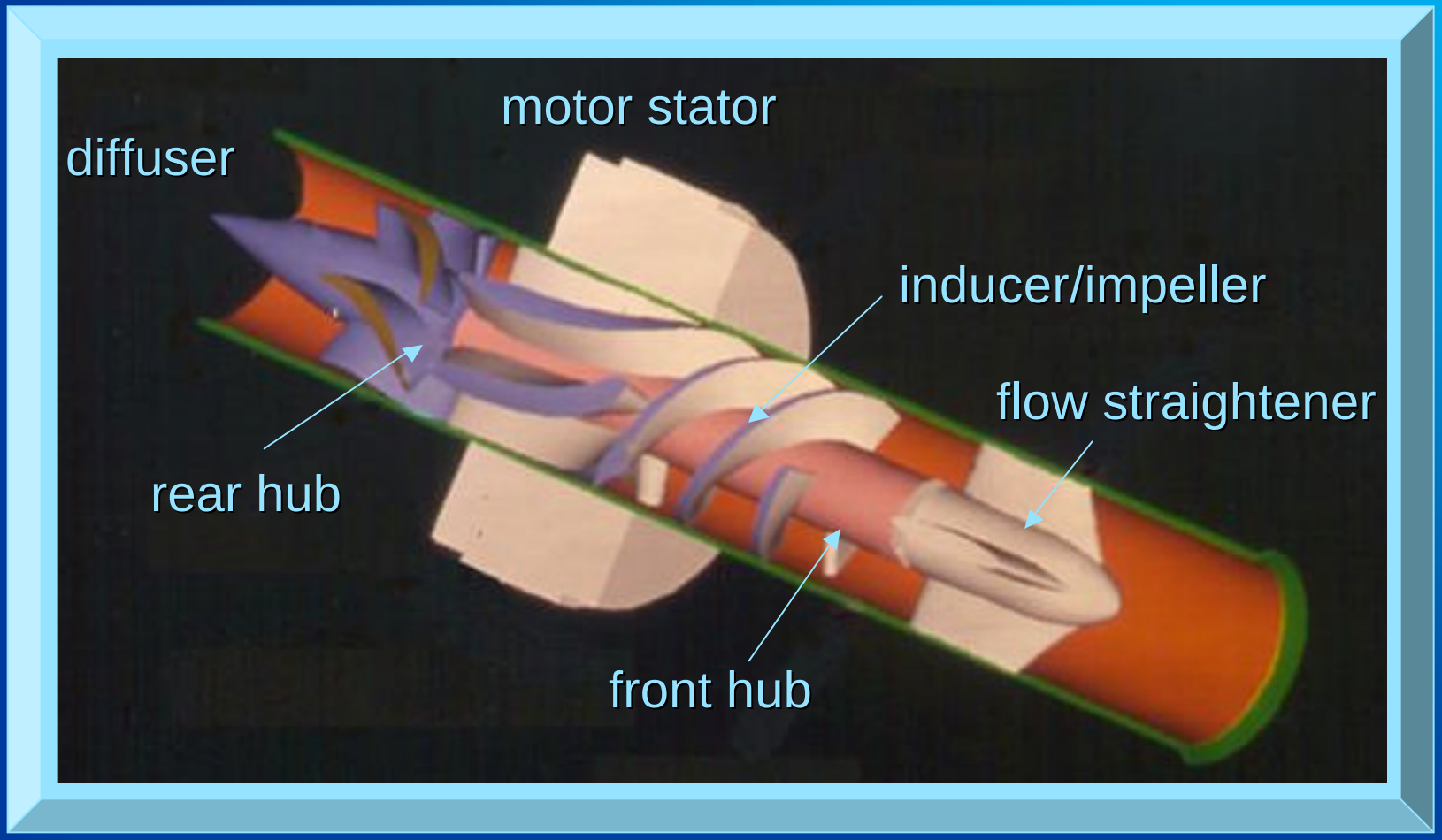
- Temporary ventricular assist to allow recovery of the natural heart
- Bridge-to-transplant until a donor heart becomes available
- Permanent ventricular assist to allow the patient to lead a normal and active life
- Component within a compact heart-lung machine

Technology Transfer

Non-medical applications may also use features or elements of the VAD™

- √ Devices requiring low power consumption
- √ Areas where space is limited or miniaturization is needed
- √ Environments in which corrosion is a problem

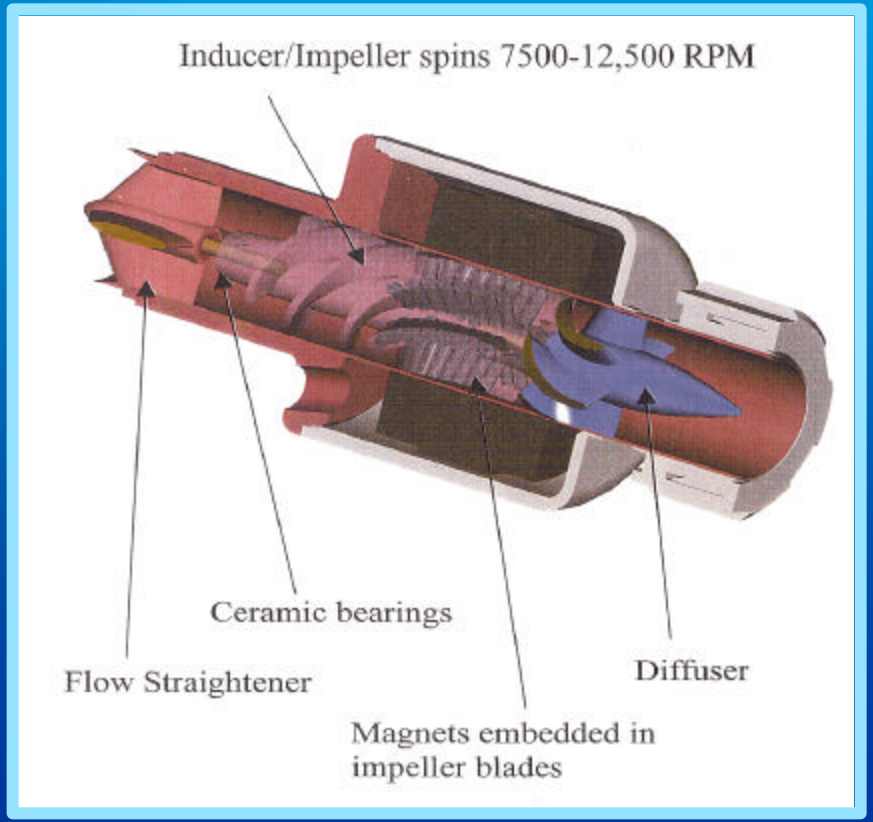
Features of the VAD™



Design Challenges

Requirements for the VAD™

- √ Hydrodynamically sound at flow rates of 5 L/min and pressures of 100 mm Hg
- √ Minimal damage to blood cells
- √ Small and fully implantable
- √ Effective for short- and long-term use
- √ Reliable, efficient, and inexpensive



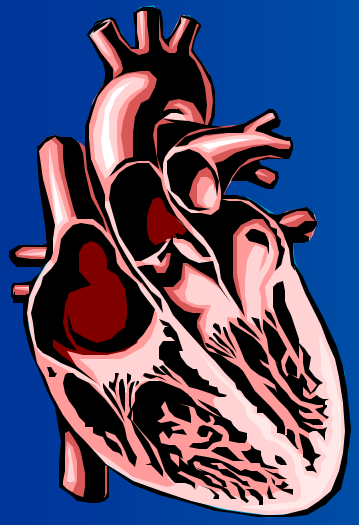
The Complete System

Dr. DeBakey with the implantable VAD™ and its external energy transfer system

Device Comparisons

Clinically Available	***Pulsatile Flow VAD***		***Axial Flow VAD***
	Heart Mate Left Ventricular Assist System	Novacor Left Ventricular Assist System	NASA/DeBakey Ventricular Assist System
Size	218cc	260cc	15cc
Values	Yes	Yes	No
Compliance Chamber	Yes	Yes	No
Weight	570 gram	1000 gram	95 gram
Required Power	10-15 Watt	10-15 Watt	6-10 Watt
Hemolysis	Not Reported	Not Reported	0.002g/100L

Human Trials

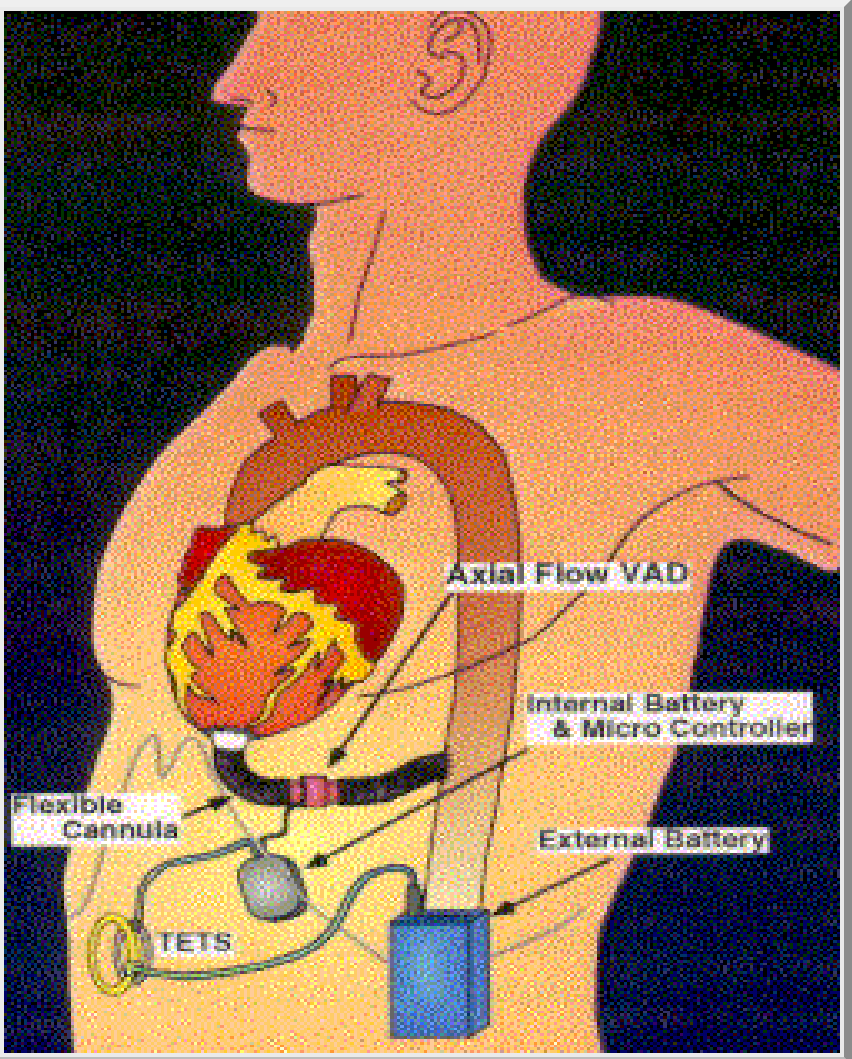


- One successful heart transplant after 75 days
- 36 successful implants in European clinical trials
- Three successful implants in US clinical trials, which began June 8, 2000
  - √ Device now FDA-approved for clinical trials
  - √ Trials have begun at The Methodist Hospital in Houston, TX
  - √ MicroMed™ Plans to expand trials in centers throughout the U.S.
  - √ MicroMed has recently established new corporate agreements that will expand the clinical utility of the DeBakey VAD™

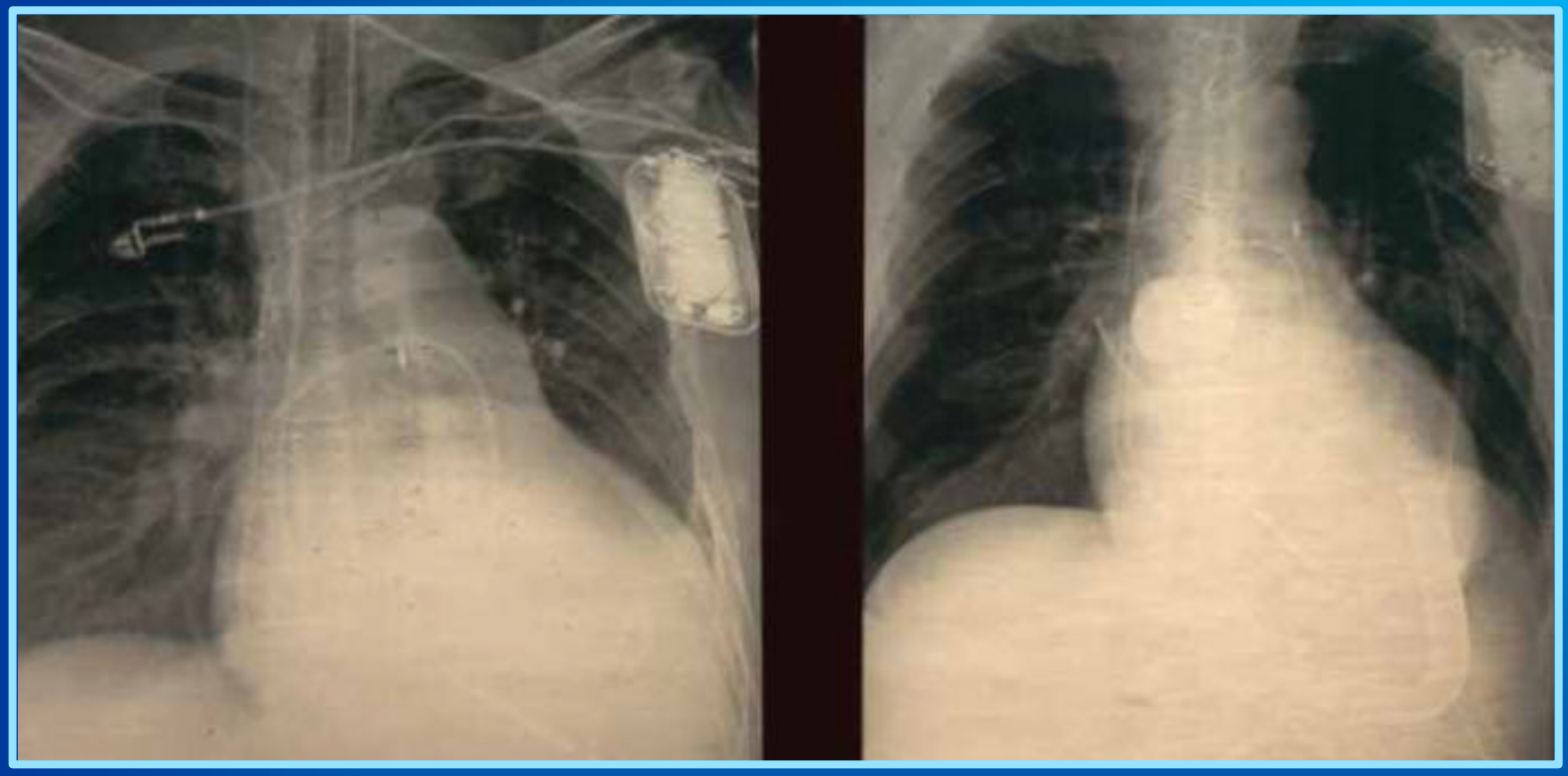
*As of 07/07/00

VAD ™ Placement

Schematic of the Axial Flow VAD™ within a human recipient



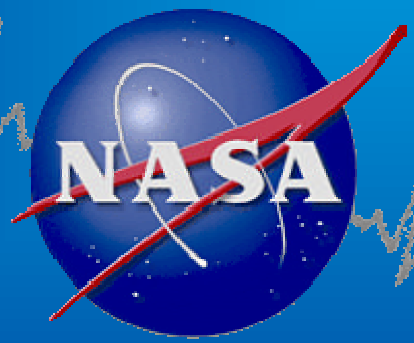
In Vivo View



The Axial Flow VAD™ can be seen inside the chest cavity of this recipient

Conclusions

By leveraging NASA's models of complex flow environments, NASA and Baylor College of Medicine have developed an invaluable medical device.



MicroMed Technologies, Inc., of Houston, Texas, is now ensuring that this device will reach thousands of patients and save an equal number of lives.

Developed by
Futron Corporation